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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,274	12/19/2001	David N. Herndon	D6197D	5877

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Benjamin Aaron Adler
Adler & Associates
8011 Candle Lane
Houston, TX 77071

EXAMINER

NGUYEN, DAVE TRONG

ART UNIT

PAPER NUMBER

1632

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DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/025,274

Applicant(s)

HERNDON ET AL.

Examiner

Dave T. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 3, 22, drawn to a gene therapy method of enhancing a would healing in an external wound in an individual, comprising injecting a cholesterol-containing cationic liposome into said, said liposome comprising a gene encoding a growth hormone.
- II. Claim 3, 4, drawn to a gene therapy method of enhancing a would healing in an external wound in an individual, comprising injecting a cholesterol-containing cationic liposome into said, said liposome comprising a gene encoding a insulin-like growth factor-I.
- III. Claim 3, 22, drawn to a gene therapy method of enhancing a would healing in an external wound in an individual, comprising injecting a cholesterol-containing cationic liposome into said, said liposome comprising a gene encoding keratinocyte growth factor.
- IV. Claim 3, 22, drawn to a gene therapy method of enhancing a would healing in an external wound in an individual, comprising injecting a cholesterol-containing cationic liposome into said, said liposome comprising a gene encoding a fibroblast growth factor.
- V. Claim 3, 22, drawn to a gene therapy method of enhancing a would healing in an external wound in an individual, comprising injecting a cholesterol-containing cationic liposome into said, said liposome comprising a gene encoding a epidermal growth factor.

- VI. Claim 3, 22, drawn to a gene therapy method of enhancing a would healing in an external wound in an individual, comprising injecting a cholesterol-containing cationic liposome into said, said liposome comprising a gene encoding a transforming growth factor-beta.
- VII. Claim 3, 22, drawn to a gene therapy method of enhancing a would healing in an external wound in an individual, comprising injecting a cholesterol-containing cationic liposome into said, said liposome comprising a gene encoding a growth hormone.
- VIII. Claim 9, 15, 19, drawn to a gene therapy method of enhancing a would healing in an external wound in an individual, comprising covering said wound with a wound coverage material, which is impregnated with a cholesterol-containing cationic liposome into said, said liposome comprising a gene encoding a growth hormone.
- IX. Claim 9, 10, 15, 16, drawn to a gene therapy method of enhancing a would healing in an external wound in an individual, comprising covering said wound with a wound coverage material, which is impregnated with a cholesterol-containing cationic liposome into said, said liposome comprising a gene encoding an insulin-like growth factor I.

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- X. Claim 9, 15, 19, drawn to a gene therapy method of enhancing a wound healing in an external wound in an individual, comprising covering said wound with a wound coverage material, which is impregnated with a cholesterol-containing cationic liposome into said, said liposome comprising a gene encoding a keratinocyte growth factor.
- XI. Claim 9, 15, 19, drawn to a gene therapy method of enhancing a wound healing in an external wound in an individual, comprising covering said wound with a wound coverage material, which is impregnated with a cholesterol-containing cationic liposome into said, said liposome comprising a gene encoding fibroblast growth factor.
- XII. Claim 9, 15, 19, drawn to a gene therapy method of enhancing a wound healing in an external wound in an individual, comprising covering said wound with a wound coverage material, which is impregnated with a cholesterol-containing cationic liposome into said, said liposome comprising a gene encoding an epidermal growth factor.
- XIII. Claim 9, 15, 19, drawn to a gene therapy method of enhancing a wound healing in an external wound in an individual, comprising covering said wound with a wound coverage material, which is

impregnated with a cholesterol-containing cationic liposome into said, said liposome comprising a gene encoding a PDGF.

XIV. Claim 9, 15, 19, drawn to a gene therapy method of enhancing a wound healing in an external wound in an individual, comprising covering said wound with a wound coverage material, which is impregnated with a cholesterol-containing cationic liposome into said, said liposome comprising a gene encoding a transforming growth factor-beta.

Claims 1, 2 are the linking claims among inventions I-VII. Claims 20, 21, 23, and 24 are linking claims among inventions I, III-VII. Claims 5-8, 11-14 are linking claims among inventions VIII-XIV. Claims 17-18 are linking claims among inventions VIII, and X-XIV. Note that the restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), as listed above. Upon the allowance of the linking claims, the restriction requirement as to the linked invention shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such (claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170

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USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Each of the inventions as claimed is directed to a distinct gene which is being used for the gene therapy method of treating an external wound. For example, a PDGF gene is not the same as a growth hormone gene. Likewise, an injection method using a liposomal carrier is not the same as inventions which are drawn to the use of a liposomal carrier impregnated in a wound coverage material or wound closure material.

Should any of Inventions VIII-XIV be elected, a following species restriction is required:

A specifically named species of a wound coverage material as listed in claim 8.

A specifically named species of a wound closure material as listed in claim 14.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of a specific named wound coverage material and a single disclosed species of a specifically named wound closure material as recited in the to be elected claimed invention even though this requirement is traversed.

Should any of Inventions I-XIV be elected, a following species restriction is required:

A specifically named species of wound as listed in claim 2, 7, or 13.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of

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specifically named species of would in the to be elected claimed invention even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, it would be unduly burdensome for the examiner to search and examine for patentability of all of the claimed inventions, and thus, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee

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required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051**.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is **(703) 305-7401**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen
Primary Examiner
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DAVE T. NGUYEN
PRIMARY EXAMINER